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WILLIAM J. REA

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BOOTH ALBANESI SCHROEDER LLC
1601 ELM STREET
SUITE 1950
DALLAS, TX 75201-4744

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SCHWADRON, RONALD B

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ldcarpenter@ipoftexas.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte WILLIAM J. REA and
BERTIE B. GRIFFITHS

Appeal 2012-009999
Application 08/902,692
Technology Center 1600

Before ERIC GRIMES, MELANIE L. McCOLLUM, and ERICA A.
FRANKLIN, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a therapeutic method, which the Examiner has rejected for lack of enablement. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

STATEMENT OF THE CASE

The Specification discloses “a method of preparing and using an autogenous lymphocytic factor (ALF). . . . The ALF is a substance derived from an individual’s own normal T and B lymphocytes isolated from a blood

sample and then propagated in a cell culture, which is then administered to the same individual. This invention modulates the abnormal function and levels of the individual's T and B lymphocytes." (Spec. 1: 11-16.)

The Specification states that the "method involves determining the initial health status of an individual. The individual's initial health is best assessed by measuring the individual's T and B lymphocyte parameters, such as measuring the individual's lymphocytic cell cycle." (*Id.* at 2: 13-15.) The Specification states that ALF can be clinically administered to an individual "to modify or regulate the individual's abnormal lymphocytic cell cycle" (*id.* at 3: 23-24).

The Specification states that "the method can be applied to the study of and/or clinical treatment of individuals suffering from a suppressed, dysfunctional, or deregulated immune system for any number of possible causes. However, the emphasis of this invention is on the treatment of the individuals who have compromised immune systems that result in an abnormal susceptibility to environmental chemicals (chemically sensitive)," among other things (Spec. 4: 11-12).

Claims 49-64, 67, and 70 are on appeal. Claim 49 is representative and reads as follows:

49. A method for treating a chemically sensitive individual having an irregular cell cycle for T lymphocytes, the method comprising the steps of:

- (a) collecting a blood sample for the individual;
- (b) determining an initial status of the cell cycle for T lymphocytes;
- (c) isolating mixed T and B lymphocytes from the blood sample;
- (d) propagating the isolated mixed T and B lymphocytes to obtain propagated lymphocytes;
- (e) lysing the propagated lymphocytes to obtain a lysate; and
- (f) administering the lysate to the individual.

The Examiner has rejected all of the pending claims under 35 U.S.C. § 112, first paragraph, for lack of enablement (Answer 5). The Examiner finds that a “chemically sensitive individual,” as recited in the claims, is also known as one having “multiple chemical sensitivity” (*id.*), and that Orme¹ states that “there is no evidence to support the use of ‘multiple chemical sensitivity’ as a diagnostic entity” (*id.* at 6). The Examiner therefore cites Orme as evidence that “it is unclear if the disease which the claimed invention treats exists as a clinical entity” (*id.*).

The Examiner also finds that the claims encompass “the treatment of a wide variety of diseases ‘caused by chemical sensitivity’ including patients suffering from dermatitis, vasculitis, asthma,” etc. (*id.*) but Hall² “discloses that the connection between ‘chemical sensitivity’ and the various diseases which the specification links to ‘chemical sensitivity’ is questionable” (*id.*). The Examiner also cites Barrett (2007)³ as “a complaint filed against Inventor Rea filed with the Texas Medical Board which questions the validity of the diagnosis and treatment of chemical sensitivity as proffered by Inventor Rea” (*id.*).

The Examiner finds that it is “unpredictable in the absence of appropriate evidence in humans to as to whether the claimed invention can

¹ Orme et al., *Multiple Chemical Sensitivity*, American Council on Science and Health, pp. 1-24 (1994), from www.ACSH.org/publications/pubID.847pub_detail.ASP

² Hall, *Environmental Medicine, Not Your Average Specialty*, Science Based Medicine, pp. 1-4 (2009), from www.sciencebasedmedicine.org/?p=2564

³ Barrett, *Disciplinary Action against William Rea, M.D.*, Casewatch, pp. 1-11 (2007), from www.casewatch.org/board/med/rea/complaint.shtml

be used to regulate an abnormal lymphocytic cell cycle” in the in vivo treatment of humans (*id.* at 7) and that “there is no evidence in the specification that such regulation has been achieved using the claimed method” (*id.*). The Examiner finds that the “only actual data disclosed in the specification wherein the cell cycle of human cells is analyzed is that represented in Figures 2-4” and that these data “suggest[] that the claimed method cannot be used to ‘regulate’ the cell cycle of abnormal lymphocytic cell cycle of continuously dividing T and B lymphocytes because the term regulate would encompass normalization of an abnormal cell cycle and this has not been demonstrated” (*id.* at 8).

The Examiner concludes that the Specification does not enable the breadth of the claimed invention . . . because the use for the instant invention disclosed in the specification is the in vivo treatment of disease in humans. The state of the art is such that is unpredictable in the absence of appropriate evidence as to how the instant invention could be used for the in vivo treatment of disease in humans.
(*Id.* at 9-10.)

Appellants argue that the claims are directed to treating “chemically sensitive” individuals, which the Specification defines by referring to symptoms (Appeal Br. 13), and which is different from the “multiple chemical sensitivity syndrome” referred to in Orme and Hall (*id.* at 14). Appellants also argue that the Specification does not assert that chemical sensitivity causes or is linked to a plethora of diseases, as the Examiner asserts (*id.* at 12). Appellants also argue that the complaint discussed in Barrett (2007) is irrelevant to the issue of enablement (*id.* at 10).

Appellants argue that the “specification evidences improvement in the cell cycle for T lymphocytes” (*id.* at 18) and that it provides adequate guidance to allow a skilled worker to practice the claimed method without undue experimentation (*id.* at 19). In support of their position, Appellants have provided a declaration under 37 C.F.R. § 1.132 of William J. Rea (filed Sept. 20, 2010, Evidence Appendix of the Appeal Brief, Exhibit A).

“Section 112 does not require that a specification convince persons skilled in the art that the assertions therein are correct.” *In re Armbruster*, 512 F.2d 676, 678 (CCPA 1975). Rather,

the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by th[e] claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement. If the PTO meets this burden, the burden then shifts to the applicant to provide suitable proofs indicating that the specification is indeed enabling.

In re Wright, 999 F.2d 1557, 1561-62 (Fed. Cir. 1993). Patentability is determined based on a preponderance of the evidence in the record. *See In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992).

After reviewing the evidence of record, we conclude that the Examiner has not provided an adequate basis for concluding that practicing the claimed method would require undue experimentation. The Specification states that “ALF . . . in the form of a lysate prepared from normal mixed T and B lymphocytes grown in cell culture” (Spec. 3: 14-15) can be used “to modify or regulate the individual’s abnormal lymphocytic cell cycle” (*id.* at 3: 23-24) and specifically for “the treatment of the

individuals who have compromised immune systems that result in an abnormal susceptibility to environmental chemicals (chemically sensitive)” (*id.* at 4: 11-12).

The Specification provides a working example of treatment of 25 individuals as normal controls and 290 other individuals, “[t]he vast majority of [whom] were chemically sensitive, chronically ill patients” (*id.* at 12: 18-20). The Specification reports that “[s]ignificant changes were typically observed in patients treated with ALF. Changes were observed in improvement of overall clinical manifestations and immune studies.” (*Id.* at 14: 1-2.) The Specification states that “[t]here was an 88% improvement ($p<0.001$) in symptoms and sign scores” for the first 100 patients (*id.* at 15: 2-3) and “[s]ignificant improvement occurred in 85% of the patients with a $p<0.001$ ” (*id.* at 20: 16-17) for the second group of 190 patients (*id.* at 19: 17).

The Specification’s disclosure is presumptively accurate, *In re Marzocchi*, 439 F.2d 220, 223 (CCPA 1971), and the Examiner has the burden of providing evidence or reasoning to rebut that presumption. *Id.* at 224. The Examiner has cited Orme and Hall as evidence that there is skepticism in the art regarding whether “multiple chemical sensitivity” is a meaningful diagnosis (Answer 5-6). However, as Appellants have pointed out (Appeal Br. 14), the Specification uses “chemical sensitivity” to mean a specific type of symptom, specifically an abnormal susceptibility to environmental chemicals resulting from a compromised immune system (*see* Spec. 4: 11-12). Orme, by contrast, states that multiple chemical sensitivity (MCS) is “intoleran[ce] to a wide range of, and possibly all, synthetic

chemicals” resulting from “repeated small exposures (or a single high exposure) to environmental agents [that] can sensitize people and cause their immune system to malfunction” (Orme 3). That is, Orme states that MCS is a result of exposure to environmental agents that *causes* the immune system to malfunction, while the Specification states that chemical sensitivity is a susceptibility to environmental chemicals *resulting from* a compromised immune system.

Orme states that MCS is referred to by several other names (*id.*) but does not state that chemical sensitivity, as used in the Specification, is the same as MCS. The Examiner cites Barrett (2005)⁴ as showing that MCS has in the past been called “chemical sensitivity” (Answer 13) but this falls short of showing that MCS is the same as chemical sensitivity, as that term is defined in the Specification. The Examiner (Answer 16) also points to a statement in Orme, which provides a definition of chemical sensitivity allegedly suggested by Dr. Rea in a publication, but again the definition in Orme differs from the definition in the Specification, and does not show that a skilled worker would have considered chemical sensitivity, as defined in the Specification, to mean the same thing as MCS.

For their part, Appellants have provided a declaration under 37 C.F.R. § 1.132 of William J. Rea. Dr. Rea declared that “[m]ultiple chemical sensitivity’ refers to *a syndrome*, not to symptoms” (Rea Declaration, ¶ 37) while “‘*chemical sensitivity*’ refers to symptoms” (*id.* at ¶ 28). Dr. Rea declared that the Specification “does *not* use the term ‘multiple chemical

⁴ Barrett, *Multiple Chemical Sensitivity: A Spurious Diagnosis*, Quackwatch pp. 1-8 (2005), www.quackwatch.org/010uackeryRelatedTopics/mcs.html

sensitivity.’ The claims are not directed to ‘multiple chemical sensitivity.’” (*Id.* at ¶ 36.) The Examiner did not respond substantively to the Rea Declaration.

The Examiner’s position that the claims are directed to treating patients with MCS is therefore not supported by a preponderance of the evidence of record. We conclude that the Examiner has not established the relevance of Orme and Hall to the method defined by the claims, and we therefore give little weight to their discussions of MCS.

The Examiner also cites Hall as evidence that it “is unclear if ALF can actually be used to treat disease (see pages 3-4)” (Answer 6). The Examiner has not, however, shown that the experiment discussed in Hall represents the same method disclosed and claimed in the instant application, nor has the Examiner shown that the positive results discussed in Hall were *not* at least partly attributable to treatment with ALF. In sum, the Examiner has not adequately shown that Orme and Hall rebut the presumption of accuracy to which the Specification is entitled. We agree with Appellants (Appeal Br. 10) that the Examiner has not shown the relevance of Barrett (2007) to the nonenablement issue on appeal.

With regard to the Examiner’s position that the claims encompass “the treatment of a wide variety of diseases ‘caused by chemical sensitivity’” (Answer 6), Appellants argue that the “specification never asserts that chemical sensitivity ‘causes’ or ‘is linked to’ a ‘plethora’ of diseases as the Examiner implies” and “the phrase ‘caused by chemical sensitivity’ . . . is not found in the specification” (Appeal Br. 12).

Dr. Rea addressed the Specification's statement that the patients treated in the working example were "chemically sensitive, chronically ill patients, including those suffering from dermatitis, vasculitis, asthma," and other disorders (*see* Spec. 12: 20-21). Dr. Rea declared that "this statement is properly interpreted as referring to the 290 individuals as having *at least* the common denominator of being chemically sensitive, not that 'chemical sensitivity . . . apparently encompasses' the listed the [sic] symptoms and diseases" (Rea Declaration, ¶ 45). Dr. Rea also declared that, "[i]n [his] opinion and experience, chemically sensitive individuals, as a class, frequently *additionally* suffer from one or more of a wide variety of other diseases. Nevertheless, other diseases are not part of the definition of 'chemical sensitivity.'" (*Id.* at ¶ 46.)

We conclude that a preponderance of the evidence of record does not support the Examiner's interpretation of the claims as encompassing treatment of a wide variety of diseases including "dermatitis, vasculitis, asthma, organic brain syndrome, gulf war syndrome or immune system specific suppression, dysfunction or deregulation and arthritis" (Answer 6). Rather, the claims are directed to treatment of "individuals who have compromised immune systems that result in an abnormal susceptibility to environmental chemicals" (*see* Spec. 4: 11-12).

In summary, the Specification states that the claimed method is effective in treating chemical sensitivity. The Specification is presumed to be accurate, and the Examiner has not provided sufficient evidence to overcome that presumption. Nor has the Examiner established that carrying out the recited steps of the claimed method, individually or collectively,

would have required more than routine experimentation. The Examiner therefore has not carried the initial burden of showing, by a preponderance of the evidence, that the claimed method is not enabled by the Specification.

SUMMARY

We reverse the rejection of claims for nonenablement.

REVERSED

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